

Remarks

I. Introduction

These remarks are submitted in response to the Non-Final Office Action dated June 12, 2007. The Applicants wish to expressly thank Examiner Stacy Brown Chen and Director Robert Wax for generously granting a personal interview to Applicants' representatives on October 25, 2007.

Claims 22, 25-27, 29 and 31-38 are pending in the application. Claims 33 has been amended by this amendment to correct antecedent basis. Support for this amendment is found, for example on page 14, paragraph 73.

No new matter had been added.

Claims 22, 25-27, 29 and 31-38 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Claim 33 was rejected under 35 U.S.C. § 112, second paragraph.

The previous rejection of claims 22, 23 and 25-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement was withdrawn by the Examiner.

Reconsideration of this application as amended, and allowance of all pending claims are hereby respectfully requested.

II. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 22, 25-27, 29 and 31-38 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that this is a new matter rejection, alleging that the specification does not appear to adequately provide support for screening kidney function for the ability to fragment protein in a patient. Applicants respectfully disagree.

Claim 22 recites: A method of screening kidney function for the ability to fragment protein in a patient comprising:

- (a) generating at least one fragmentation profile for at least one protein from a urine sample obtained from the patient;
- (b) comparing said at least one fragmentation profile with a reference fragmentation profile for said at least one protein of a normal individual ; and
- (c) correlating a decrease in fragmentation of the at least one protein with decreased kidney function.

As discussed in the interview of October 25, 2007, the specification clearly discloses the screening of kidney function for the ability to fragment protein in a patient by correlating a decrease in fragmentation of a protein or proteins with decreased kidney function. For example, on page 1, paragraph 3, the specification sets out that “The appearance of excess protein such as albumin in the urine is indicative of kidney disease . . . Therefore it is an object of the invention to provide a test that is more sensitive than the currently known radioimmunoassay to detect such a disease as early as possible so that the disease can be either prevented or a treatment protocol commenced early on in the disease,” and “The applicant has discovered that in renal disease fragmentation of proteins is inhibited. This means that substantially full-length fragmentation of proteins is inhibited”, (page 7, paragraph 34), “The presence of albumin in the urine is a sign that functions of the kidney may be impaired. Once this level begins to change, treatment may be initiated,” (page 14, paragraph 77).

Moreover, the specification teaches “In a preferred aspect of the present invention, the method of determining a propensity for or early diagnosis of a kidney disease in a subject is determined before the subject becomes microaluminuric,” (page 16, paragraph 85), “Thus, a normal individual would provide a distinct fragmentation profile indicative of an absence of kidney disease or no propensity for a kidney disease . . . The fragmentation profile begins to

change and more products in the region of full-length albumin manifests as additional spikes or an enlarged peak indicative of more intact/modified albumin in the urine," (page 16, paragraph 16), and "Detecting modified protein using the method according to the invention is a more effective method for predicting the onset of a renal disease than using conventional RIA," (page 25, paragraph 136).

From the above sections of the specification, it is clear that the purpose of the claim steps, (screening kidney function for the ability to fragment protein) by correlating a decrease in fragmentation of at least one protein with decreased kidney function, was clearly contemplated at the time of filing.

Therefore, withdrawal of the rejection and allowance the claims is respectfully requested.

III. Claim Rejections – 35 U.S.C. § 112, second paragraph

Claim 33 was rejected under § 112, second paragraph as allegedly being indefinite for failing to point out and distinctly claim the subject matter regarded as the invention. In particular, the Examiner asserts that the claim lacks antecedent basis. It is respectfully submitted that the amendment to claim 33, obviates this rejection.

For all of the foregoing reasons discussed above, it is urged that the application is in condition for allowance, an indication of which is respectfully solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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